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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,961	07/19/2002	Maria DeMoragas	C 2041 PCT/US	8959

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COGNIS CORPORATION
PATENT DEPARTMENT
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EXAMINER	
GOLLAMUDI, SHARMILA S	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,961	DEMORAGAS ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Preliminary Amendments and Foreign Priority Papers received on February 19, 2002 is acknowledged. Claims **11-30** are pending in this application. Claims 1-10 stand cancelled.

Information Disclosure Statement

The information disclosure statement filed fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the two references cited as non-patent literature and are not initialed on the PTO 1449 do not have an English abstract or a translation. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1). However, the other references cited have been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 11 and 21 recite "an active substance in the form of a chitosan microcapsule" which is vague and indefinite since it is unclear whether the chitosan capsule

itself is the active substance or if the chitosan microcapsule itself contains an active substance within. If the latter is the intended limitation, the examiner suggests rephrasing the limitation to read "at least one active substance encapsulated within in a chitosan microcapsule" or "a chitosan microcapsule containing at least one active substance."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by FR 2699545 (abstract).

FR '545 discloses a gelling agent (capsule) for cosmetics and pharmaceuticals, which acts as a thickener and stabilizer. The gelling agent comprises at least one chitosan and at least one partial alkyl alginate. The gels encapsulate polar active substances, for example fatty acids, triglycerides, essential oils, etc.. see abstract.

Claims 11, 20, 21, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Dumitriu et al (5,620,706).

Dumitriu et al disclose a chitosan-xanthan gum microcapsules that encapsulate an enzymes or drugs in the proportion up to 25%. See column 2, lines 10-11. The gels are utilized in internal and external use (skin patches). See column 12, lines 60-61.

Note that the preamble "method of enhancing the stability and dermatological compatibility of a decorative cosmetic composition" occurs in the preamble and the body of the claim is able to stand alone and does not depend on the preamble for completeness. Therefore, is

not given patentable weight. Further, since the prior art teaches the same composition containing a chitosan microcapsule, the prior would inherently provide recited stability and compatibility.

Claims 11, 20, 21, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by DE 19712978 (abstract).

DE discloses cosmetic and pharmaceutical formulations containing chitosan microspheres. The microspheres encapsulate an oily component. Further, the microspheres have high biocompatibility and regular surface to provide a pleasing appearance. See abstract.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12-19 and 22-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dumitriu et al (5,620,706) in view of Tsang et al (4,663,286).

Dumitriu et al discloses that hydrogels are made by polycationic and polyanionic compounds. The use of natural polyanionic substances such as alginates, heparin, carrageenan,

and pectin, in the formation of complexes with polycations such as chitosan, is known. See column 2, lines 57-67. Dumitriu et al disclose a chitosan-xanthan (gel former) gum microcapsules that encapsulate an enzymes or drugs in the proportion up to 25%. See column 2, lines 10-11. The hydrogel spheres are prepared by contacting a xanthan gum solution with a chitosan solution. See examples. The gels are utilized in internal and external use (skin patches). See column 12, lines 60-61.

The reference does not teach an additional anionic polymer to form the microcapsule.

Tsang et al teach encapsulation of materials. A core material, such as cells, are encapsulated by a gelling polymer, (alginate) with a polyvalent cation to form a shape retaining gel mass. The gel mass is then coated with a second membrane (post-coat) with a polyanionic polymer such as alginate. See abstract. This post-coating with a polyanionic polymer such as sodium alginate substantially removes the tendency of the capsules to clump. The polymer reacts with the residual cationic sites on the capsule and causes a negative polarity. Tsang discloses that it is known in the art that negative surfaces may also inhibit growth and attachment of the cells contained within. See column 6, lines 22-40.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Dumitriu et al and Tsang et al and utilize an anionic polymer during the process of forming the chitosan microcapsules. One would be motivated to do so since Tsang teaches the use of an anionic polymer coating provides a negative surface polarity, which reduces the clumping of the capsules. Therefore, it would have been obvious to utilize instant polymer to provide a clump free formulation.

Note that the product-by-process claims are given weight to the extent that the microcapsule requires three components: chitosan, a gel-former, and an anionic polymer. However, the actual process of making the product, i.e. dispersing the matrix in an oil phase, etc., is not given weight since the

patentability of the claims is determined by the product and not the process in which it is made, unless the applicant can show that the process provides for a structurally different product.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11, 14-15, 17, 19, and 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,733,790, optionally in view of Jones et al (5,510,120). Although the conflicting claims are not identical, they are not patentably distinct from each other because the y are obvious modifications of each other and encompass the similar subject matter.

Instant application claims a cosmetic preparation containing chitosan microcapsules. The chitosan microcapsule is prepared by providing a matrix comprising a gel former, an anionic polymer, and at least one active substance, dispersing the matrix in an oil phases, and contacting the dispersed matrix with an aqueous solution of chitosan and removing the oil phase. Dependent claims recite the anionic polymer is selected from alginic acid or anionic chitosan derivative.

US patent '790 claims a microcapsule having a matrix of at least one active principle and the microcapsule is made by the steps: forming an aqueous matrix solution of a gel former, an

anionic polymer (alginic acid or an anionic chitosan), and an active, and adding the solution to an aqueous solution of chitosan.

Jones et al teach a cosmetic preparation for topical application containing liposomes or microcapsules with a carrier. The particle contains an active agent and is mixed with a vehicle to act as a dilutant, a dispersant, or carrier for the particles so as to facilitate distribution of the particles on the site of application. See column 5, lines 44-55.

Although, the instant application recites the preamble "a cosmetic preparation", which is not accorded, containing chitosan microcapsules and US patent claims a microcapsule, both are directed to similar subject matter, the same chitosan microcapsule with the oblivious modification of a carrier. It would have been obvious to one of ordinary skill in the art to place the microcapsules of US patent '790 in a carrier to provide for a formulation since it is well known in the art that active ingredients are administered for topical administration utilizing conventional carriers. One would b motivated to do so to facilitate topical application. Additional motivation to do so is to have the carrier act as a dilutant and dispersant for the particles as taught by Jones et al.

Claims 11-13, 16, 18, and 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,733,091, optionally in view of Jones et al (5,510,120). Although the conflicting claims are not identical, they are not patentably distinct from each other because the y are obvious modifications of each other and encompass the similar subject matter.

Instant application claims a cosmetic preparation containing chitosan microcapsules. The chitosan microcapsule is prepared by providing a matrix comprising a gel former, chitosan, and

at least one active substance, and contacting the matrix with an aqueous solution of an anionic polymer. Dependent claims recite the anionic polymer is selected from alginic acid or anionic chitosan derivative.

US patent '091 claims a microcapsule having a matrix of at least one active principle and the microcapsule is made by the steps: forming an aqueous matrix solution comprising a gel former, chitosan, and at least one active substance, and contacting the matrix with an aqueous solution of an anionic polymer (alginic acid or anionic chitosan derivative).

Jones et al teach a cosmetic preparation for topical application containing liposomes or microcapsules with a carrier. The particle contains an active agent and is mixed with a vehicle to act as a dilutant, a dispersant, or carrier for the particles so as to facilitate distribution of the particles on the site of application. See column 5, lines 44-55.

Although, the instant application recites the preamble "a cosmetic preparation", which is not accorded, containing chitosan microcapsules and US patent claims a microcapsule, both are directed to similar subject matter, the same chitosan microcapsule with the oblivious modification of a carrier. It would have been obvious to one of ordinary skill in the art to place the microcapsules of US patent '091 in a carrier to provide for a formulation since it is well known in the art that active ingredients are administered for topical administration utilizing conventional carriers. One would b motivated to do so to facilitate topical application. Additional motivation to do so is to have the carrier act as a dilutant and dispersant for the particles as taught by Jones et al.

Claims 11-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 23 of copending

Application No. 10/018922, claim 23 of 10/018731, optionally in view of Jones et al (5,510,120). Although the conflicting claims are not identical, they are not patentably distinct from each other because the y are obvious modifications of each other and encompass the similar subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Instant application claims a cosmetic preparation containing chitosan microcapsules. The chitosan microcapsule is prepared by providing a matrix comprising a gel former, an anionic polymer, and at least one active substance, dispersing the matrix in an oil phases, and contacting the dispersed matrix with an aqueous solution of chitosan and removing the oil phase. Instant application also claims a cosmetic preparation containing chitosan microcapsules. The chitosan microcapsule is prepared by providing a matrix comprising a gel former, chitosan, and at least one active substance, and contacting the matrix with an aqueous solution of an anionic polymer. Dependent claims recite the anionic polymer is selected from alginic acid or anionic chitosan derivative.

Co-pending application 10/018731 recites a microcapsule prepared by providing a matrix comprising a gel former, chitosan, and at least one active substance, and contacting the matrix with an aqueous solution of an anionic polymer. The anionic polymer is selected from alginic acid or anionic chitosan derivative.

Co-pending application 10/018922 recites a microcapsule prepared by providing a matrix comprising a gel former, an anionic polymer, and at least one active substance, dispersing the

matrix in an oil phases, and contacting the dispersed matrix with an aqueous solution of chitosan and removing the oil phase.

Jones et al teach a cosmetic preparation for topical application containing liposomes or microcapsules with a carrier. The particle contains an active agent and is mixed with a vehicle to act as a dilutant, a dispersant, or carrier for the particles so as to facilitate distribution of the particles on the site of application. See column 5, lines 44-55.

Although, the instant application recites the preamble "a cosmetic preparation", which is not accorded, containing chitosan microcapsules and US patent claims a microcapsule, both are directed to similar subject matter, the same chitosan microcapsule with the oblivious modification of a carrier. It would have been obvious to one of ordinary skill in the art to place the microcapsules of US patent '091 in a carrier to provide for a formulation since it is well known in the art that active ingredients are administered for topical administration utilizing conventional carriers. One would b motivated to do so to facilitate topical application. Additional motivation to do so is to have the carrier act as a dilutant and dispersant for the particles as taught by Jones et al.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:00), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616

SSG

MICHAEL G. HARTLEY
PRIMARY EXAMINER